

MTC's ENDOSCOPE

Courtesy of Bedeman Laser Institute.



● MTC's endoscope will be used in cancer drug trials in 1998.

BMDO HISTORY

Another beneficiary of the BMDO-funded Medical Free Electron Laser (MFEL) program was Robert Alfano, Ph.D., at the City College of New York (New York, NY). Alfano is a physicist who has studied the optical properties of living tissue for a number of years. His recent work in visible light transmission through breast tissue has attracted considerable attention.

Cancers of the mouth and

esophagus are largely

preventable through

lifestyle changes such as

smoking cessation and

limited alcohol use. It is

imperative to catch the

disease early to prevent

development of potentially

disfiguring and life-threat-

ening lesions.

Early in the MFEL program, however, Alfano experimented with the native fluorescence of tumor cells as compared with their normal counterparts. Fluorescence spectroscopy is an up-and-coming technology that is widely expected to become an integral part of cancer diagnosis within the next few years. Along with Mediscience Technology Corporation (MTC; Cherry Hill, NJ), Alfano devised an endoscopic tool that could be inserted into the mouth and esophagus to look for signs of cancer as determined by the fluorescence signature of the mucosal lining. This tool, the CD-Scan and CD-Ratiometer, will be evaluated in a major clinical trial at the Memorial Sloan-Kettering Cancer Center in New York City.

HOW IT WORKS

MTC's devices use a fiber-optic probe to illuminate tissue with a laser or other light source and a spectrometer to analyze the fluorescence that results from the illumina-

tion. Increasing numbers of investigators in oncology are finding that there are discernible and very useful differences between malignant and normal tissue fluorescence signatures. Trials such as those described below are necessary to correlate these signatures with conventional microscopic means of cancer diagnosis to create a useful clinical database. Consistent results that match fluorescence signals with cancer evidence mean that some future biopsies will be performed with light rather than scalpels. This database is growing significantly.

MEDICAL SIGNIFICANCE

In a previous report, we noted that MTC was planning an investigational device exemption (IDE) application for its device, which it obtained in early 1997. Stimson P. Schantz, M.D., an otolaryngologist at Sloan-Kettering who specializes in cancers of the head and neck, is using the CD-

Scan and CD-Ratiometer as part of his patients' clinical evaluations in a Phase II drug trial. A new and promising vitamin A derivative, 13-*cis*-retinoic acid, is being tested as a treatment for oral leukoplakia, a whitish lesion of the mouth that can progress to cancer. The CD-Scan will be used to corroborate excisional biopsy findings with the unique fluorescence signal of the precancerous lesion. The device will also be used in a Phase III trial that will follow the completion of the Phase II trial.

In addition, the U.S. Army Medical Research, Development, Acquisition, and Logistics Command will be using a fiber-optic needle and the CD-Ratiometer to diagnose breast cancer via needle biopsy techniques. As in Schantz's trial, the device will be used along with conventional histopathology methods to determine the fluorescence signals associated with breast malignancies. This trial will be conducted at Massachusetts General Hospital (Boston, MA). The principal investigator is radiologist Daniel B. Kopans, M.D.

MTC is also planning to file an IDE for detecting gastrointestinal premalignancy with the CD-Scan device.

VENTURES OR PRODUCT AVAILABILITY

MTC has 15 patents in the area of biomedical optics. The CD-Scan and CD-Ratiometer are based on its patented tissue fluorescence technology. MTC is also working with the City University of New York and General Electric to develop a non-ionizing optical mammography system, although optical techniques for this application are in the very earliest stages of development. MTC has received private equity financing from Allen and Company, an investment banking company, to carry out its research activities.

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